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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,713	06/20/2003	Takeshi Koizumi	5328-12	7563

27799 7590 06/30/2006

COHEN, PONTANI, LIEBERMAN & PAVANE  
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NEW YORK, NY 10176

EXAMINER

BAUSCH, SARAE L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/601,713

Applicant(s)

KOIZUMI ET AL.

Examiner

Sarae Bausch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/30/2006 has been entered.

2. Currently, claims 1, 4 and 9 are pending in the instant application. Claims 2-3, 5-8, and 10-11 have been cancelled. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action.

***Priority***

3. Acknowledgment is made of applicant's prior foreign application, Japan 2002-003912. It is noted that applicants are not claiming priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Japan on 01/10/2002, since the United States application was filed more than twelve months thereafter.

***Withdrawn Rejections***

4. The rejections of claims 1 and 4, under 35 U.S.C. 102, made in section 8, of the previous office action mailed 11/30/2005, is withdrawn in view of the evidence presented by applicant (see Model 380B DNA Synthesizer in the response mailed 05/30/2006).

***Declaration***

5. The declaration under 37 CFR 1.132 filed 05/30/2006 is sufficient to overcome the rejection of claims 1 and 4 based upon reference, Model 380B DNA Synthesizer provided by applicant in the declaration.

***New Grounds of Rejections***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahlberg et al. (US Patent 5888780 March 1999).

With regard to claim 1, 4, and 9, Dahlberg et al. teach a method of asymmetric PCR using 100 pmole of biotin-labeled sense primer SEQ ID No. 42 and 1 pmole of fluorescein-labeled antisense primer (see column 69, lines 4-20). Dahlberg et al. teach the nucleic acid may be labeled at either the 5' or 3' end with a nonisotopic label, such as digoxigenin or biotin (claim

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1 and 4) (see column 35, lines 40-62). Dahlberg et al. teach primer SEQ ID No. 42 is 5' labeled with biotin (see column 65, lines 60-62).

***Maintained Rejections***

***Claim Rejections - 35 USC § 102***

8. Claims 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Sorensen (J. Virology, Dec 1993, p. 7118-7124). It is noted that this rejection was previously presented in section 8, of the previous office action mailed 11/30/2005 and is reiterated below.

With regard to claim 9, Sorensen et al. teach a method that comprises PCR amplification by providing a biotinylated provirus-specific primer and a partly degenerate arbitrary primer (instant claim 4) with a fixed 3' end which will hybridize (instant claim 5) within a statistically defined range in the cellular DNA flanking the provirus (see 1<sup>st</sup> column, 3<sup>rd</sup> paragraph, page 7118) (figure 1 and 2). The primers used for amplification and hybridization have a biotin coupled to the 5' end of the primer (see figure 1A and 1C).

***Response to Arguments***

9. The response asserts in the response mailed, 05/30/2006, that Sorensen et al. does not recite PCR primer that is degenerate and biotinylated. This response has been thoroughly reviewed but not found persuasive. Claim 9 recites a method comprising providing a PCR primer that comprises a biotin at the 5' terminus and amplifying said target DNA fragment via PCR using said PCR primer wherein said PCR is either one of asymmetric PCR or degenerate PCR. The claim does not recite wherein said PCR *primer* is either one of asymmetric PCR

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primer or degenerate PCR primer. The claim further is drawn to a method comprising providing a PCR primer that comprises biotin at 5' terminus. The recitation of "comprising" allows for additional primers within the method. Sorensen et al. discloses degenerative PCR amplification using a PCR primer that comprises a biotin at the 5' terminus, see page 7120, 1<sup>st</sup> column, last paragraph and figure 1. Therefore, Sorensen et al. anticipates claim 9.

For these reasons, Sorenson et al. anticipates claims 9.

### *Conclusion*

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

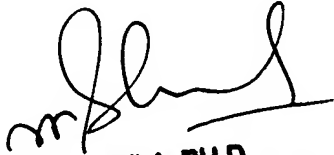
Any inquiry of a general nature or relating to the status of this application

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or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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**RAM R. SHUKLA, PH.D.**  
**SUPERVISORY PATENT EXAMINER**



**Sarae Bausch, PhD.**  
**Examiner**  
**Art Unit 1634**